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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,379	07/01/2003	Oliver Hobert	5199-92	7972

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EXAMINER

GAMETT, DANIEL C

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,379	Applicant(s) HOBERT, OLIVER	
	Examiner Daniel C. Gamett, PhD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 11-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The amendments of 06/27/2005 have been entered in full. Claims 1-40 are pending. Claims 11-39 have been withdrawn from consideration. Claims 1-10 and 40 are under examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn

3. Rejection of Claims 4 and 6 under 35 U.S.C. 102(b) as being anticipated by Sulston, Accession No. AL132876.4, November 15, 1999, is withdrawn in view of Applicant's amendments.

Claim Rejections Maintained

4. Claims 4, 6, 8, and 10 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid having the sequence of SEQ ID NO: 1 and the rh133, n561 and n2400 mutant alleles thereof, recombinant vectors, cells, and methods of making the encoded protein, does not reasonably provide enablement for the mutant nucleic acids, proteins, vectors, cells, and methods of Claims 4, 6, 8, and 10. Applicant's arguments filed 06/27/2005 have been fully considered but they are not persuasive. The amended base claim 4 to include the limitation "wherein the isolated nucleic acid encodes for a mutant chloride intracellular channel protein." Applicant argues that, with this functional limitation, the claims no longer encompass a limitless number of variants and that, in view of the state of the art at the time the invention was made, the specification provides adequate disclosure for a skilled artisan to make the claimed nucleic acids. However, the set of all missense mutations, nonsense mutations, point mutations,

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substitutions, deletions, insertions, polymorphisms, or rearrangements of the sequence of SEQ ID NO:1 is very large and would be expected to include a large number of non-functional embodiments. Testing each one for the described activity would require undue experimentation.

Claim Rejections - 35 USC § 112, necessitated by Applicant's amendment

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A nucleic acid that has (comprises) as few as 2 consecutive nucleotides from SEQ ID NO:1 would meet the limitation “a sequence of an exc-4 mutant allele”. Thus the claim encompasses an uncertain number of variants that may bear little resemblance to the reference sequences; the metes and bounds of the claim cannot be determined. This rejection could be obviated by replacing the indefinite article *a* with *the*.

New Grounds of Rejection

7. Upon further consideration, prior indications of allowability are withdrawn.
8. Claims 1-10 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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9. Claims 2, 3, 5, 7, and 9 depend from claim 1, which is drawn to an isolated nucleic acid having the sequence of SEQ ID NO.: 1 *or a sequence complementary to SEQ ID NO.: 1*, wherein the sequence of SEQ ID NO.: 1 encodes a *C. elegans* chloride intracellular channel protein (emphasis added). A nucleic acid that has (comprises) as few as 2 consecutive nucleotides complementary to SEQ ID NO.: 1 would meet the emphasized limitation, as it is SEQ ID NO.: 1, not the claimed complementary sequence, that must encode a channel. Thus, claim 1 encompasses a large genus of polynucleotides.
10. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of an indefinite degree of complementarity to a reference sequence. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.
11. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly

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allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

12. With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotide, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.
13. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.
14. Furthermore, with regard to the PNA of claim 2, there is no identification of any portion of SEQ ID NO: 1 or its complements that should be incorporated into a PNA. Indeed, there is no evidence that applicants are in possession of a PNA that meets the limitations of claim 2.
15. With regard to claims 4, 6, 8, 10, and 40, it is not known how large the genus of all missense mutations, nonsense mutations, point mutations, substitutions, deletions, insertions, polymorphisms, or rearrangements of the sequence of SEQ ID NO:1 or *any* sequence of the rh133, n561 and n2400 mutant alleles (claim 40) that could encode a channel is. This potentially large genus is represented in the instant specification by only SEQ ID NO: 1 and the rh133, n561 and n2400 mutant alleles.

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16. Therefore, only isolated polynucleotides comprising the nucleic acid sequence set forth in SEQ ID NO: 1, and the specific variants that define the rh133, n561 and n2400 mutant alleles, but not the full breadth of the claim meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion


17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG
Art Unit 1647
16 September 2005


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SUPERVISORY PATENT EXAMINER
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